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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,029	08/27/2003	Jeffrey M. Ondra	DEP5108USA	6457
27777 7590 03/05/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER				
BLANCO, JAVIER G				
ART UNIT		PAPER NUMBER		
3774				
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03/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/650,029

Applicant(s)

ONDRLA ET AL.

Examiner

JAVIER G. BLANCO

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11,12,14-17,19,21-24,26-31 and 41 is/are pending in the application.

4a) Of the above claim(s) 26 and 41 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,2,4-9,11,12,14-17,19,21-24 and 27-31 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 4, 11, 14, 21 in the reply filed on December 10, 2007 is acknowledged.
2. Applicants' cancellation of claims 3, 10, 13, 18, 20, 25, and 32-40 in the reply filed on December 10, 2007 is acknowledged.
3. Applicants' filing of formal drawings in the reply filed on December 10, 2007 is acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 14, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Regarding claim 4, the limitation "said ring" is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (crescent-shaped). Further, "said ring" lacks antecedent basis.
 - b. Regarding claim 14, the limitation "said ring" is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (crescent-shaped). Further, "said ring" lacks antecedent basis.

c. Regarding claim 26, the limitation “said ring” is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (crescent-shaped). Further, “said ring” lacks antecedent basis particularly since claim 25 has been cancelled.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-9, 11, 12, 14-17, 19, 21-24, 27-31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Masini** (US 6,267,785 B1; cited in Applicants’ IDS).

Referring to Figures 3-7, Masini discloses a positioning fixture *for positioning* at least one of a trial and a prosthesis (see column 7, lines 4-23) in the medullary canal (cavity 312) of a long bone (bone 315), said fixture comprising:

- a. A body (assembly comprising collar 330, assembly comprising ring 406, assembly comprising clamp 550); and
- b. First, second, and third members (**Figure 3**: thumb screws 332 attached to collar 330, gasket 334, and/or rod 342; **Figure 4**: thumb screws attached to ring 406 and/or rods 408/420 having collar 422, see column 6, lines 15-18; **Figure 5**: thumb screws 552/554 attached to clamp 550, rods 520/540, and/or bolt 506) *for cooperation* with the body.

Said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal, said member *adapted to support* at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figure 3**: external periphery of stem, ring 350, and/or bore through longitudinal axis of trial/prosthesis; **Figure 4**: ring 350 and/or external periphery of stem; **Figure 5**: bore through longitudinal axis of trial/prosthesis and/or external periphery of stem; **Figure 6**: fin having cross-bores). As shown in Figures 3 and 5, the body is generally crescent-shaped. As shown in Figure 4, the body is ring-shaped. With regards to dependent claim 4, see Figure 5 wherein the first portion is the main body of clamp 550 and the second portion (movably attached to the first portion) is screw 546. The “securing feature” could be the inner/inside wall of the body, which frictionally engages (“for securing”) the fixture to the long bone.

The intended use recitations (e.g., “adapted to extend”, “for at least partially surrounding”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Masini ‘785 is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

8. Claims 1, 2, 5-9, 11, 12, 15-17, 19, 21-24, and 28-31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Kenyon et al.** (US 5,342,362 A).

Referring to Figures 1-4, 7, 10, and 11, Kenjon et al. disclose a positioning fixture (adaptor 30 and/or indicator 110) *for positioning* at least one of a trial and a prosthesis in the medullary canal of a long bone, said fixture comprising:

- a. A body (**Figures 7, 10 and 11**: assembly comprising clamp 124); and
- b. Members (**Figures 7, 10 and 11**: anchor pin 96) *for cooperation* with the body.

As shown in Figures 7, 10, and 11, the body comprising a crescent-shaped member (e.g., clamp 124) and is capable of at least partially surrounding the long bone. Said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal, said member *adapted to support* at least one of the trial (see Figure 10) and the prosthesis (see Figure 11) as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figures 7, 10 and 11**: transversal grooves and/or longitudinal grooves on stem 6, 100). With regards to claim 4, the “first portion” is one end of the body, and the “second portion” is the other end of the body, wherein one end is “movably attached” (broadly interpreted as “if one portion moves, the other portion moves as well”) to the other end. Also, housing 32 comprises leg 35 and arm 36 (see Figures 1-3). The “securing feature” could be the inner/inside wall (or an external portion or surface) of the body, which frictionally engages (“for securing”) the fixture to the long bone. Also, the “securing feature” could be nipples 48 and/or arms 44,46 (Figures 1-3) or connection port 116 (Figures 7, 10, and 11).

The intended use recitations (e.g., “adapted to extend”, “for at least partially surrounding”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Kenyon et al. ‘362 is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

9. With regards to the 102(b) rejection based on **Masini** (US 6,267,785 B1; cited in Applicants’ IDS), Applicants’ arguments filed December 10, 2007 have been fully considered but they are not persuasive.

a. Regarding the functional or intended use limitation “*adapted to extend through at least a portion of the long bone*”, the Applicants argue “the set screws 332 of Masini are not adapted to extend through at least a portion of the long bone into the medullary canal”. The Examiner respectfully disagrees.

As seen in Figure 3, any of thumb screws 332 is adapted to extend through at least a portion of the long bone. As seen in Figure 5, any of thumb screws 552/554 attached to clamp 550, rods 520/540, and/or bolt 506 is adapted to extend through at least a portion of the long

bone. It is noted bolt 506 (see Figure 5) extends from the body of the positioning fixture. Further, if a person skilled in the art continues turning (e.g., screwing) a pin or screw into a bone it will eventually be adapted to extend through the cortical bone and into the medullary canal.

b. The intended use recitations (e.g., “adapted to extend”, “for at least partially surrounding”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Masini ‘785 is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. With regards to the 102(b) rejection based on **Kenyon et al.** (US 5,342,362 A), Applicants’ arguments filed December 10, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue Kenyon et al. ‘362 do not disclose the body as comprising a crescent-shaped member. The Examiner respectfully disagrees. As shown in Figures 7, 10, and 11, the body comprises a crescent-shaped member (e.g., clamp 124) and is capable of at least partially surrounding the long bone.

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b. The intended use recitations (e.g., “adapted to extend”, “for at least partially surrounding”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Kenyon et al. ‘362 is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738